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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/405,735	09/24/1999	GERALD B. PIER	B0801/7155	9816

7590 11/19/2002  
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EXAMINER

SIEW, JEFFREY

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 11/19/2002

16

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/405,735

Applicant(s)

PIER, GERALD B.

Examiner

Jeffrey Siew

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 03 September 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-68 is/are pending in the application.
- 4a) Of the above claim(s) 1-13 & 44-68 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Election/Restrictions*

1. This application contains claims 1-13 & 44-68 are drawn to an invention nonelected with traverse in Paper No. 8/3/01. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 14-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- A) The term "therapeutically effective amount" renders claims 14-25 indefinite because it is unclear as to what disease the preparation is to be therapeutic for. Consequently the effective amount is indeterminate.

The term is still indefinite because the added language upregulating CFTR expression does not further clarify as the amount by which an amount would be therapeutically effective for what disease or infection. The rejection is maintained.

B) Claims 26-43 are confusing because it is unclear whether the claims scope may also be inclusive of fatty acid portions of LPS structure.

The term comprising opens the language to encompass more than the recited structure. In claim 14 the term lipid core moiety limits the structure to contain only lipid core moiety which would not contain the LPS but claims 26 & 36 do not recite such language.

### *Claim Rejections - 35 USC § 102*

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 26-43 are rejected under 35 U.S.C. 102(a) as being anticipated by Masoud et al (J. of Bacteriology Dec. 1995 pp. 6718-6726).

Masoud et al teach the isolation of lipopolysaccharide core of P. aeruginosa (see whole doc.). They teach that the core contains an alanine (see Table 2 & Figure 8 & 9).

The term "bioactive agent" and "covalent conjugate" are interpreted broadly to include the polysaccharide portions of the lipopolysaccharide.

Art Unit: 1656

The response states that Masoud et al do not teach the claimed the structures. Figure 9 appears to teach the lipid core structure. Moreover the response states that Masoud et al do not teach non toxic agent. Masoud et al also teach portions of lipid core that are covalently bound to polysaccharide and vaccine derivatives of core glycolipid antigen (see Table 2). Moreover the response states that the Masoud et al do not teach binding to CFTR. Claims 26-43 do not recite such language. The rejection is maintained.

**THE FOLLOWING IS A NEW GROUND OF REJECTION NECESSITATED BY THE  
AMENDMENT**

***Claim Objections***

A) Claim 14 appears to have alanine at the incorrect location. It should be bound to GalN.

B) In claim 32 Hepp is misspelled.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14-25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for therapeutic amount for clearing pseudomonas infection, does not reasonably provide enablement for all infections or diseases. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

In Ex parte Forman, 230 USPQ 546 (Bd. App. 1986), the Board considered the issue of enablement in molecular biology. In considering these factors: (a) in order to practice the invention, the practitioner must make and use a therapeutically effective amount of CFTR expression regulator for upregulating CFTR expression for any disease or infection ; (b) the specification provides guidance therapeutical amounts for clearance of pseudomonas infections; (c) working examples are presented LPS core enhances P. aeruginosa infections (see page 35); (d) the invention is directed to treating all infections and diseases by administering therapeutically effective amount of CFTR expression regulator for upregulating CFTR expression for any disease or infection ; (e) the prior art teaches that core structure of LPS from P. Aeruoginosa. ; (f) the level of skill in the pharmaceutical technology and disease treatment is high; (g) the results of experiments involving lung clearance and CFTR mechanism is not predictable; (h) the claims are broadly drawn, reciting any possible treatment of disease . Based on the above analysis, one of ordinary skill in the art would be subject to undue experimentation in using and making a therapeutically effective amount of CFTR expression regulator for upregulating CFTR expression for any disease or infection.

### SUMMARY

5. No claims are free of the prior art but rejected under 112 1<sup>st</sup> and second paragraph. It is suggested that claim 14 be amended to recite a therapeutical amount for P. auroginosa infection as an avenue toward allowable subject matter.

### CONCLUSION

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Siew whose telephone number is (703) 305-3886 and whose e-mail address is Jeffrey.Siew@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner is on flex-time schedule and can best be reached on weekdays from 6:30 a.m. to 3 p.m. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703)-308-1119.

Any inquiry of a general nature, matching or filed papers or relating to the status of this application or proceeding should be directed to the Tracey Johnson for Art Unit 1637 whose telephone number is (703)-305-2982.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal

Application/Control Number: 09/405,735

Page 7

Art Unit: 1656

Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Center numbers for Group 1600 are Voice (703) 308-3290 and Before Final FAX (703) 872-9306 or After Final FAX (703) 30872-9307.

  
JEFFREY SIEW  
PRIMARY EXAMINER

November 17, 2002